



# **Department of Veterans Affairs Office of Inspector General**

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## **Healthcare Inspection**

### **Alleged Quality of Care Issues in the Electroconvulsive Therapy Program VA Boston Healthcare System Boston, Massachusetts**

**To Report Suspected Wrongdoing in VA Programs and Operations:**

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## Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review to determine the validity of allegations made by a confidential complainant regarding quality of care and other issues related to the electroconvulsive therapy (ECT) program and Mental Health (MH) Service at the VA Boston Healthcare System (the system).

The complainant alleged that patients were not medically optimized prior to ECT and that a patient underwent ECT without consent or the knowledge that ECT could be refused. Additional allegations included improprieties related to ECT machine maintenance, ECT research, inpatient MH unit census, and electronic medical record (EMR) access.

We did not substantiate that a psychiatrist did not medically optimize two patients prior to ECT resulting in adverse events. Both patients had pre-existing conditions, and staff provided appropriate treatment on the morning of ECT. We did not substantiate that staff provided ECT treatment to a patient without obtaining his consent or informing the patient that he could refuse treatment. The EMR reflects several provider-patient discussions, as well as the patient's decisions regarding ECT treatments.

We substantiated that although local maintenance was performed annually, the ECT machine was not sent to the manufacturer every 2 years for a full quality control check and that some patients were re-scheduled because of equipment malfunctions. We did not substantiate that a psychiatrist did not optimize a high risk patient prior to ECT in an effort to emphasize ECT side effects and promote a research drug in lieu of ECT. We also did not substantiate that the psychiatrist was conducting research of any kind.

We did not substantiate that an inpatient MH unit had a lower census to benefit a researcher and a research assistant who was a relative of the Inpatient MH Director. We also did not substantiate that the research assistant inappropriately breached the system's e-mail. The research assistant appropriately acknowledged her relationship with the Inpatient MH Director and completed all VHA requirements for electronic access. We substantiated that a psychiatrist initiated, but did not complete, EMR notes for residents she supervised. The notes could not be completed until signed by the residents. We did not substantiate the allegation that the psychiatrist had special privileges which allowed in-depth computer access.

We recommended that the System Director implement procedures to ensure that the manufacturer's recommended maintenance for the ECT machine is followed as prescribed.



**DEPARTMENT OF VETERANS AFFAIRS**  
**Office of Inspector General**  
**Washington, DC 20420**

**TO:** Director, VA New England Healthcare System (10N1)

**SUBJECT:** Healthcare Inspection—Alleged Quality of Care Issues in the Electroconvulsive Therapy Program, VA Boston Healthcare System, Boston, MA

## **Purpose**

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) conducted an inspection to determine the validity of allegations made by a complainant concerning the VA Boston Healthcare System (the system). The complainant alleged improper electroconvulsive therapy (ECT) practices, nepotism in patient assignment of admissions and transfers from acute to chronic inpatient mental health (MH) units, and research improprieties.

## **Background**

### **VA Boston Healthcare System**

The system is part of Veterans Integrated Service Network (VISN) 1 and comprises three campuses, including Jamaica Plain, West Roxbury, and Brockton. In addition, the system has five community based outpatient clinics located in Worcester, Framingham, Quincy, Lowell, and downtown Boston.

The system has 448 acute care, 160 community living center, and 46 domiciliary beds. Inpatient MH services are located at the Brockton campus, and ECT is provided at the Brockton and Jamaica Plain campuses. The system received Centers of Excellence Awards for its Cardiac Surgery, Post Traumatic Stress Disorder (PTSD), Women's Health, Seriously Mentally Ill, and Substance Abuse programs. Additional programs provided by the system include Geriatric Research Education and Clinical Center, Homeless Veterans Treatment and Assistance, Persian Gulf Veterans, Preservation/Amputation Care and Treatment, Prosthetic and Sensory Aids, Readjustment Counseling, and Spinal Cord Injury. The system has affiliations with Harvard Medical School and Boston University School of Medicine.

## Allegations

A complainant contacted the OIG Hotline Division in August 2010 and January 2011 alleging:

- Improper ECT practices at the system. The complainant wrote that “ECT is the most safe and efficacious treatment when practiced safely. The most safe and efficacious treatment is being limited to our Veterans and instead safety concerns remain.” The complainant alleged that many times ECT was provided in a manner that increased health risks and posed substantial danger to veterans. In a subsequent clarifying discussion, the complainant alleged that a psychiatrist at the system did not medically optimize patients prior to performing ECT treatments. Specifically, the complainant alleged that patients were not treated with their usual cardiac and anti-hypertensive medications on the mornings of their ECT treatment in order to optimize cardiovascular status. It was further alleged that this resulted in adverse events for two patients. The complainant also alleged that the Director of Inpatient MH was aware of, and agreed with, such practice at the system.
- A Brockton campus psychiatrist provided ECT to a patient without the patient’s consent and with knowledge that the patient could refuse ECT.
- The ECT machine had not been sent to the manufacturer for required maintenance in years, and multiple equipment failures were experienced. The complainant alleged that local maintenance of the ECT machine by system staff did not substitute for manufacturer-performed maintenance. MH leadership reportedly received notice in 2009 of the importance of adhering to an ongoing required maintenance regimen of the ECT device, but MH leadership was slow to take action.
- A psychiatrist doing research on a “Mental Health Diagnostic Study” since June 2010 did not give antihypertensive medication to a subject patient before ECT treatment. Because the patient was not medically optimized before receiving ECT, the patient should not have been included in the study. It was further alleged that the psychiatrist’s research study was sponsored by a pharmaceutical company, that the company wanted its medication used in lieu of ECT, and that the psychiatrist included patients in the study to show that ECT caused cardiac side effects.
- A chronic inpatient MH unit received fewer patient admissions and transfers, and the unit maintained a lower patient census in exchange for provision by a unit clinician of research training to a relative of the facility’s Director of Inpatient MH. In addition, it was alleged that this relative breached patient confidentiality by inappropriately accessing the system’s e-mail.

- A psychiatrist at the Brockton campus opened patient electronic medical record (EMR) notes under other clinicians' accounts without their knowledge or consent. It was further alleged that this psychiatrist had special Automatic Data Processing Application Coordinator (ADPAC) privileges that allowed the psychiatrist in-depth computer access, which is more than usual or needed privileges.

## Overview of ECT

ECT is a procedure used in the treatment of certain MH conditions. During ECT, electrodes are placed on the patient's scalp and a brief electric stimulus is applied while the patient is anesthetized in order to induce a short, controlled seizure. Clinical indications for ECT include (among others) severe depression or mania that does not respond to medication or counseling, catatonia, and psychotic exacerbations in schizophrenia when the psychotic symptoms in the present episode have an abrupt or recent onset.<sup>1</sup>

## American Psychiatric Association (APA) ECT Task Force Report

According to a task force report of the American Psychiatric Association, *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training, and Privileging*, ECT is often administered to patients with severe medical illnesses accompanying their psychiatric illness(es). Nevertheless, ECT may be the treatment of choice in some medically ill patients because of its speed of action and safety profile. There are no absolute medical contraindications to ECT. Instead, an assessment of the relative risks and benefits of ECT should be undertaken in each individual case. Some medical conditions significantly increase the risk of ECT treatment and, in treating such high-risk patients with ECT; attempts should be made to improve and stabilize medical conditions as well as to decrease the level of risk at the time of ECT treatments. Careful medical evaluation is an important component of this process.<sup>2</sup>

Conditions that may be associated with increased risk of ECT include recent heart attack, unstable angina, poorly compensated congestive heart failure, severe valvular cardiac disease, aneurysm or vascular malformation that may be susceptible to rupture with increased blood pressure, increased intracranial pressure (as may occur with some brain tumors), recent stroke, severe chronic obstructive pulmonary disease, asthma, pneumonia, and patient status rated as a level 4 or 5 on the American Society of Anesthesiologists (ASA) physical status classification.<sup>3</sup> The use of certain medications may also be associated with increased risk.<sup>4</sup>

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<sup>1</sup> *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training, and Privileging*. A Task Force Report of the American Psychiatric Association, 2<sup>nd</sup> edition, American Psychiatric Association, Washington, DC, 2001, p.23–25.

<sup>2</sup> Ibid, p.27–30.

<sup>3</sup> The ASA physical classification system is used to assess the degree of a patient's sickness or physical state prior to selecting an anesthetic or prior to performing surgery. The system is also used for record keeping purposes,

The type and severity of pre-existing cardiac disease affects the likelihood and severity of cardiac complications during ECT. The cardiovascular risks of ECT derive primarily from the marked changes in the heart rate and blood pressure that generally occur during and immediately after the electrical stimulus and induced seizure. All patients referred for ECT who have clinically significant cardiovascular disease should have an electrocardiogram (EKG), a chest x-ray, and measurement of serum electrolytes as part of the pre-ECT evaluation.<sup>5</sup>

When death occurs with ECT, it typically happens immediately following the seizure or during the post-seizure recovery period. Cardiovascular and pulmonary complications are the leading cause of death. Given the high rate of cardiac arrhythmias in the immediate post-seizure period, most of which are benign and resolve spontaneously, EKGs should be monitored during and immediately after ECT.<sup>6</sup>

Reports of stroke during or shortly after ECT are “surprisingly rare, given the magnitude of hemodynamic changes that occur during the treatment and the number of patients with cerebrovascular disease who receive ECT.” The APA Task Force report recommends that care should be taken to avoid hypotension in patients with ischemic cerebrovascular disease who are receiving ECT and that short-acting antihypertensive medications should be considered at the time of treatment for patients at risk for hemorrhagic cerebrovascular events (such as aneurysms).<sup>7</sup>

The Task Force report indicates that “regardless of the type and degree of cardiovascular disease, [medical] optimization prior to ECT should be attempted, keeping in mind any risks that may be associated with delaying the start of ECT. Unless there is clear evidence to the contrary, current medications likely to diminish cardiovascular risk with ECT should be continued, including administration prior to ECT, when such medication would have been provided in any case.”<sup>8</sup>

Some medications may be taken in the morning before ECT while others should be withheld until the patient recovers from a treatment session. Pre-ECT orders for each treatment should specify medications and dose to be administered or withheld before the treatment. “In general, medications thought to exert a protective effect with respect to

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communication between colleagues, and to create a uniform system for statistical analysis. It is not intended as a measure to predict operative risk. ASA 1: Normal healthy patient. ASA 2: Patients with mild systemic disease. ASA 3: Patients with severe systemic disease. ASA 4: Patients with severe disease that is a constant threat to life. ASA 5: Moribund patients who are not expected to survive without the operation. Source: Cleveland clinic website: [http://my.clevelandclinic.org/services/anesthesia/hic\\_asa\\_physical\\_classification\\_system.aspx](http://my.clevelandclinic.org/services/anesthesia/hic_asa_physical_classification_system.aspx), accessed on 6/15/11.

<sup>4</sup>*The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training, and Privileging*. A Task Force Report of the American Psychiatric Association, 2<sup>nd</sup> edition, American Psychiatric Association, Washington, DC, 2001, p.27–30.

<sup>5</sup>*Ibid*, p. 27, 35–37, 54–55.

<sup>6</sup>*Ibid*, p 60.

<sup>7</sup>*Ibid*, p. 28, 53–54, 60.

<sup>8</sup>*Ibid*, p. 36–37.



ECT-induced changes and those necessary to optimize medical status should be given prior to the treatment.”<sup>9</sup> Examples include anti-hypertensives, anti-angina medications, certain anti-arrhythmic drugs, anti-gastroesophageal reflux medications, bronchodilator medications for asthma or chronic obstructive pulmonary disease (except theophylline); and certain glaucoma medications. Although the intention behind pre-ECT administration of such medications is to enhance safety, the psychiatrist and anesthesiologist should be aware of the potential for negative interactions and should use clinical judgment in the context of the patient’s clinical presentation.<sup>10</sup>

Shortly before each ECT treatment, the anesthesiologist administers a brief, general anesthetic and a muscle relaxant. The muscle relaxant is used to minimize convulsive motor activity (such as flailing of arms and legs) and to improve airway management.<sup>11</sup>

The Task Force recommends that anesthesia providers and ECT psychiatrists be familiar with pharmacologic strategies to prevent or treat adverse cardiovascular responses to ECT. Pharmacologic modifications (during ECT) of the cardiovascular response to ECT have their own risks, and judgment is needed about when and how to employ these strategies. For patients who are unequivocally at risk for vascular complications, such as those with unstable aneurysms, it is prudent for the anesthesiologist to administer medication as a prophylactic measure during treatment in order to blunt the hemodynamic changes that accompany seizure induction.

In patients with unstable hypertension and other cardiac conditions, an attempt should be made to stabilize the medical condition before beginning ECT. “In most patients with or without other preexisting cardiac illness, many practitioners will forego in-treatment prophylaxis and monitor cardiovascular changes closely at the initial treatments. The occasional sustained hypertension or significant arrhythmia after seizure induction is then treated acutely, and prophylaxis is considered for subsequent treatments.”<sup>12</sup>

A good working relationship with the anesthesia provider, consultation with a physician with expertise in assessment and treatment of cardiac disease, and understanding of the cardiovascular effects of ECT are helpful in optimizing management of patients with cardiovascular conditions.<sup>13</sup>

## **System Policy**

According to system policy,<sup>14</sup> when an ECT consult is generated by a clinician, an ECT psychiatrist must review the patient’s EMR, evaluate the patient, and discuss potential

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<sup>9</sup>Ibid, p. 81–82

<sup>10</sup>Ibid, p. 81–82.

<sup>11</sup>Ibid, p.132–136.

<sup>12</sup>Ibid, p.136–139, 184–185.

<sup>13</sup>Ibid, p.185.

<sup>14</sup>A Boston Healthcare System, Patient Care Memorandum 116A-003-MH, “Administration of Electroconvulsive Therapy (ECT),” dated September 2010.

risks and benefits of ECT with the patient's attending physician. If a psychiatrist confirms that ECT is indicated, an informed consent must be obtained from the patient or guardian after adequate discussion. The Chief of Psychiatry or designee will then write or co-sign a progress note containing the indications and contraindications for ECT and will indicate concurrence or non-concurrence with pursuing this treatment modality.

The policy also requires that all patients receive a pre-ECT medical workup within 30 days prior to the initial ECT treatment. The workup must be documented in the EMR prior to the first ECT treatment and should include a comprehensive medical history and physical examination. If not completed by a staff attending internal medicine physician, then a separate comprehensive history and physical examination by a staff attending internal medicine physician is required within 30 days of the first ECT treatment.

Although system policy does not require specific laboratory work, recommended minimum laboratory work includes a complete blood count, electrolytes, urinalysis, a pregnancy test, and additional laboratory work when indicated to be obtained within 30 days prior to the first acute phase treatment. An EKG and chest x-ray are recommended if indicated because of the presence of known cardiopulmonary disease or other reasons. An x-ray of the thoraco-lumbar spine and dental consultation may also be obtained if clinically indicated. Additionally, the policy requires providers to document any history of drug sensitivity to anesthetic agents and family history of problems associated with the use of succinylcholine in general anesthesia.

Following the medical workup and before the first treatment, a psychiatrist refers the patient for an initial evaluation by the Anesthesiology Section. Any relevant changes in the patient's medical status should be documented by the psychiatrist or anesthesiologist when the patient is re-evaluated prior to each subsequent treatment. A psychiatrist writes needed orders for ECT and administers or supervises the ECT treatment in the procedure room with the assistance of the Anesthesiology Section.

Depending on clinical circumstance, ECT may be provided on an inpatient or outpatient basis. Patients often receive an initial course of treatments 2–3 times per week during the acute treatment phase. After an index series of treatments (for example, 2 times per week for 5 weeks), some patients receive continuation or maintenance ECT treatments on an intermittent basis (for example, weekly or monthly) for a period of time.

## **Scope and Methodology**

On November 16–17, 2010, and February 8–9, 2011, OHI inspectors conducted site visits to the Brockton, Jamaica Plain, and West Roxbury campuses. We interviewed the complainant, system managers, MH leadership, system patient safety officer, and clinicians and staff with knowledge of the system's ECT program and MH inpatient units at the Brockton campus. We reviewed patient EMRs and the paper anesthesia records for the two patients identified by the complainant as having experienced adverse events

alleged to be related to ECT. In addition, we reviewed a barcode medication administration system (BCMA) record for one of the patients who was an inpatient at the time of ECT treatment. We reviewed pertinent system documents and applicable system and Veterans Health Administration (VHA) policies. We reviewed relevant sections of the APA Task Force report on ECT.

We obtained a list of all 19 patients who received ECT at the Jamaica Plain campus from October 1, 2009, to November 10, 2010, and reviewed EMRs for these patients looking for occurrence of ECT related adverse events. We interviewed system anesthesiologists who participate in pre-ECT clearance and provision of anesthesia during ECT treatments. We conducted follow-up telephone interviews with a representative for the complainant and system clinical staff. Additionally, on March 2, 2011, OHI Inspectors met with an outside expert consultant for a general discussion of prevailing guidelines regarding pre-ECT workup, medical clearance, treatment with cardiovascular and anti-hypertensive medications on the day of ECT treatments, and intra-treatment management of hemodynamic changes.

We reviewed work orders submitted and/or completed on the ECT machine. We also reviewed the manual that accompanies the machine and spoke with a system technician and the manufacturer to clarify the recommended maintenance schedule. We interviewed the system's Institutional Review Board (IRB) administrator and related staff. We obtained a spreadsheet of all IRB approved research protocols active during the time period relevant to the allegations as well as presently active protocols. We met with the Clinical Information Systems Manager (CISM) at the Brockton campus regarding EMR access and access control issues.

We reviewed eight patient EMRs looking for notes titled "Mental Health Diagnostic Study." We interviewed the VA National MH Director for Informatics (VANMHDI).

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

## **Case Summaries**

### **Patient 1**

The patient was an elderly male with a history of major depression with psychotic features (versus bipolar disorder), PTSD, and generalized anxiety disorder. He received maintenance ECT from 1997 through 2005, as other measures, including inpatient hospitalization and medication adjustment, failed to maintain remission. He was initially treated with ECT in 1997 after being hospitalized for refractory psychotic depression. From 1997 through 2005, the patient received a total of 105 ECT treatments. The patient and his family requested a trial off of ECT in 2005, and the patient was able to maintain

stability with a gradual decrease in the frequency of treatments and subsequent discontinuance of ECT. The patient had a history of severe, catatonic-like depressions with frequent MH hospitalizations during the 1990s and in 2001.

The patient's other medical problems included early dementia, hypertension, a history of intermittent atrial fibrillation, osteoarthritis, urinary incontinence, cataracts, parkinsonism, and a history of vitamin B12 deficiency. In addition, he was noted to have a history of prior stroke, transient ischemic attacks, and arrhythmias.

Past hospitalizations were noted to be lengthy and depression symptoms "if unchecked rapidly they have on most occasions progressed to catatonia, both rigid and frenetic/alternating, frank psychosis."

In the late winter/early spring of 2010, the patient's family called the MH clinic to report that the patient had very low energy during the previous 4–6 weeks. The patient had also been experiencing increased anxiety and had been mostly staying in bed. Initially, an increase in the patient's lithium dose (a mood stabilizing medication) was tried with improvement in his symptoms but also with development of some toxicity symptoms for which the dose was adjusted back down to his original dose. The patient was briefly hospitalized for a fall and encephalopathy<sup>15</sup> and was subsequently transferred to a community rehabilitation facility where he worked on strengthening his legs. He was discharged in May 2010.

The patient initially did well after discharge from the rehabilitation facility but after a week, he became increasingly more anxious, depressed, and socially isolative and began making comments that he was going to die. The patient presented with his family to the urgent care clinic at the Brockton campus for evaluation and was admitted to the acute MH unit for mood stabilization.

During this MH hospitalization, the patient reported that his depression was "very, very bad" and that he had no reason to live. The admitting psychiatrist, who had treated the patient in 2004 and 2005, offered a course of ECT, but the patient declined. At that point in time, the patient's family was noted to feel ambivalent about ECT and preferred to use it as a last resort if necessary. He was continued on his psychiatric regimen, which he had been on since at least 2005 and included lithium, an anti-psychotic medication, and an anti-anxiety medication.

In late May 2010 while on the inpatient unit, the patient was noted to be unresponsive in his chair with his head back. His breathing and airway were maintained, and he was

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<sup>15</sup>Encephalopathy is a syndrome (which may be reversible) with many possible causes (such as infection, tumor, or metabolic imbalance) in which brain function or structure is disrupted. Hallmarks include altered mental state and a decreased level of sensorium. Depending on type and severity, neurological symptoms include memory loss, impaired concentration, lethargy, personality changes, muscle twitching, tremor, loss of ability to speak, among others.

given oxygen. An EKG indicated first degree atrioventricular block.<sup>16</sup> An emergency code blue was initiated, and he was transferred to a community hospital. After being medically cleared at the outside hospital, the patient was transferred back to the Brockton campus the following day. An EKG at the community hospital reportedly showed no evidence of a heart attack, and a computerized tomography (CT) scan of the head showed no evidence of an acute event such as a stroke.

By early June, the patient was not eating well and was confused and stiff on physical examination. The patient did not have a fever, and his blood pressure and pulse were stable. However, laboratory blood tests indicated an elevated white blood cell count, dehydration, and an elevated creatine phosphokinase level.<sup>17</sup> Concerned that the patient may have an infection or neuroleptic malignant syndrome (NMS),<sup>18</sup> staff transferred the patient to a medical ward where clinicians diagnosed the patient with intermittent atrial fibrillation and encephalopathy and treated him with intravenous fluids, antibiotics, and other medication.

The patient's symptoms improved, and by mid-June he was less rigid, more alert, and interactive; however, he began to mumble words about dying and killing himself. While on telemetry (heart monitor) he was noted to have intermittent atrial fibrillation, which was treated with intravenous medication. There was no longer rigidity on exam, and he had been switched to oral antibiotics for the pneumonia and oral metoprolol (a beta blocker) for his intermittent atrial fibrillation. The patient's family (his durable power of attorney) reported that he had expressed paranoid delusions and that the family was in favor of pursuing ECT treatment, as in the past "this had in fact been a miracle for the pt [sic patient]." The patient continued to be unable to feed himself. He was transferred back to the inpatient MH unit at the Brockton campus.

As the patient's medical condition stabilized, the patient's treatment team obtained an ECT consult. The patient's psychiatrist (who was also Board certified in internal medicine) felt that the patient would benefit from ECT but noted that the most recent chest x-ray indicated the presence of a new infiltrate. The psychiatrist advised:

. . . anesthesia and I do not perform ECT on patients with active pneumonia as it is UNSAFE for the patient with a pneumonia to have General Anesthesia in the presence of active pneumonitis as it markedly increases the risk of respiratory complications from General Anesthesia for ECT,

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<sup>16</sup>In first-degree heart block, the heart's electrical signals are slowed as they move from the atria to the ventricles (the heart's upper and lower chambers, respectively). This results in a longer, flatter line between the P and the R waves on the EKG. First-degree heart block rarely causes any symptoms, and it usually does not require treatment. Source: [http://www.nhlbi.nih.gov/health/dci/Diseases/hb/hb\\_types.html](http://www.nhlbi.nih.gov/health/dci/Diseases/hb/hb_types.html) accessed on June 22, 2011.

<sup>17</sup>Creatinine Phosphokinase is an enzyme chiefly found in the brain, skeletal muscles, and heart. An elevated level can be seen in heart attacks, in conditions that damage the skeletal muscles or brain, trauma, and other medical conditions including neuroleptic malignant syndrome.

<sup>18</sup>Neuroleptic malignant syndrome is a rare, but life-threatening idiosyncratic reaction to a neuroleptic (type of anti-psychotic medication) characterized by fever, muscular rigidity, altered mental status, and autonomic instability.

with the most common complication being extension of the pneumonia to other previously uninfected areas, but there is also an increased risk of hypoxia and even respiratory arrest during the anesthesia for ECT for patients with pneumonia.

The psychiatrist recommended repeating a chest x-ray and stipulated that, prior to initiation of ECT, the repeat chest x-ray would need to be free of infiltrates. In addition, because the patient's treatment team determined he was in need of a surrogate decision maker, the psychiatrist wanted to meet with the patient's family regarding pre-ECT consent. Thirdly, the psychiatrist wanted to discuss the patient's fragile health status and recent pneumonia with the Anesthesia Section.

Laboratory blood work was obtained, and a repeated chest x-ray showed no evidence of pneumonia. The patient was seen by an internal medicine resident and discussed with an attending internal medicine physician who assessed his medical status. The assessment reviewed the patient's long list of medical problems and ongoing medical issues. The note documents that the patient's assessment, clinical data including physical exam, labs, and EKG were discussed with the attending internal medicine physician in detail and "there are no specific medical contraindications to the proposed ECT."

The following day, an attending anesthesiologist evaluated the patient, assigned an ASA score of 3, and noted that the patient was "medically clear" with multiple medical problems but no history of coronary artery disease.

The patient continued to have severe depression with psychotic symptoms and paranoid delusions. A family meeting was held with the patient and his inpatient provider, inpatient social worker, psychiatrist, and son. An ECT treatment was scheduled for the following morning. In the ECT consultation note, the psychiatrist wrote:

The patient should be NPO after midnight on the night prior to ECT. Absolutely essential medications (such as antihypertensives, cardiac medications, H2 blockers) can be given with a sip of water on the morning of ECT—in this patient's case that would mean that his metoprolol (a cardiac and blood pressure medicine in the beta blocker family) should be given with a sip of water on ECT mornings prior to his departure for ECT, but other a.m. medications should be held and either omitted or given upon return from ECT.

The note was co-signed by the designee for the Director of Inpatient MH who reviewed the case and discussed it with the attending psychiatrist. The patient was not on any psychiatric medications at that point in time.

The patient had an ECT treatment at Jamaica Plain campus the next morning (10:47 a.m.). The patient was given intravenous esmolol (a beta blocker) for post-ictal

(after a seizure) hypertension and tachycardia. Anesthesia noted stable hemodynamics, smooth emergence, and no complications. The patient was stable and alert and signed out to post anesthesia care unit (PACU). A nursing note in the PACU indicated that the patient was fully awake, able to move four extremities, and able to maintain oxygen saturation on room air with stable vital signs. The patient was transferred back to the inpatient MH unit at the Brockton campus.

Later in the day, the patient ate half of his dinner and drank fluids. The following day, nursing noted that he was up in a wheelchair trying to propel himself at times. In the evening, he was yelling for the nurse, appearing psychotic, staring at the ceiling, talking to himself, waving his hands, and was repositioned several times for comfort. Around midnight, the patient developed a low grade fever and was sent to urgent care for evaluation. The medical officer on duty (MOD) examined the patient and obtained a chest x-ray and blood work. His impression was possible aspiration pneumonia in a frail man. The plan was to obtain cultures, start antibiotics, and elevate the head of the patient's bed.

Upon return to the MH unit the patient was restless and slept in the hall for closer observation by nursing staff. He fell asleep around 3:00 a.m. While taking his vital signs at 5:40 a.m., nursing noted he was not using his left arm or hand and was attempting to move around using only the right side of his body. The MOD was notified. Evaluation revealed new facial asymmetry and no upper and lower extremity strength on the patient's left side. Staff called 911, and the patient was sent to a community hospital for evaluation for a possible stroke. Serial CT scans at the community hospital demonstrated developing right sided infarcts. A magnetic resonance imaging scan (MRI) of the head obtained a few days later showed multiple subacute ischemic infarcts of the right brain hemisphere. The clinician determined that the patient had a right middle cerebral artery stroke.

## **Patient 2**

The patient was a man in his mid-60s whose medical history included obstructive sleep apnea, paroxysmal atrial fibrillation, chronic hepatitis, diverticulosis, and a history of gallbladder surgery. The patient also had a history of depression for which he was receiving maintenance ECT every 6 weeks at the White River Junction VA Medical Center (VAMC).

A cardiology consult in May 2010 stated that the patient had a several year history of symptomatic paroxysmal atrial fibrillation. He had a history of bradycardia (slow heart rate) on an event monitor with pauses up to more than 3 seconds while on a beta-blocker. Because the beta-blocker may have contributed to the bradycardia, it had been discontinued and he had been switched to diltiazem (a cardiac medicine in a different family called calcium channel blockers). At the time of the consult, the patient's heart rate was under control, but since he was symptomatic with palpitations and fatigue, he

was interested in pursuing treatment to control his heart rhythm. The cardiologist suggested treatment alternatives including pacemaker implantation and use of an anti-arrhythmic medication or an atrial fibrillation radioablation procedure.

Because of the long distance from his home to White River Junction, the patient requested to receive his periodic outpatient maintenance ECT treatments at the Jamaica Plain campus. An outpatient ECT referral was made in late June.

In early July, the patient underwent a left atrial ablation at the West Roxbury campus. After the ablation, he was started on amiodarone (an anti-arrhythmic medication). He was also discharged on metoprolol.

In early August, an internal medicine attending physician saw the patient for a pre-ECT evaluation. At the time of the visit, the patient was back in atrial fibrillation. It was unclear to the internist if the patient was taking amiodarone or both amiodarone and metoprolol, so the internist asked the patient to bring his medications in the following Monday in order to clarify. The patient was also on warfarin (a blood thinner used to prevent blood clots to which patients with atrial fibrillation are at risk). Because an International Normalized Ratio (INR)<sup>19</sup> blood test was elevated, which indicated his warfarin dose needed to be decreased, the internal medicine consultant recommended holding off from ECT until his INR blood test was in the therapeutic range.

The following Monday, the patient was seen by his cardiac electrophysiologist who noted that the patient's EKGs showed sinus rhythm (normal) and runs of atrial flutter. The cardiologist noted improvement in symptoms and that runs of paroxysmal atrial flutter were common after an ablation procedure. The plan was to observe for 3–6 months and consider a repeat ablation procedure if the runs of atrial flutter continued. The cardiologist recommended continuing amiodarone but suggested holding off on a beta blocker like metoprolol because the patient's heart rate in the past had been slow and symptomatic, which might complicate plans for ECT.

The same day, a psychiatrist saw the patient and noted a diagnosis of bipolar disorder. The following day, the psychiatrist documented that the patient had been optimally stabilized in his cardiac status by the cardiac clinics and that maintenance ECT procedures would be adjusted in relation to cardiac demands. ECT treatment which had been previously scheduled for the day was cancelled and re-scheduled for late August to allow for adjustment of his warfarin and evaluation of repeated blood work.

A few weeks later, the patient was seen by another psychiatrist who obtained an informed consent and reviewed the patient's EMR and treatment history at the White River Junction VAMC. The patient was sent to the laboratory to have blood drawn to re-check his INR level. The second psychiatrist noted that the patient's previously elevated INR

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<sup>19</sup>A test which measures the effectiveness of anticoagulation treatment.



blood test was now good from the point of view of general anesthesia. The second psychiatrist also documented that the INR level (1.9) was slightly low (normal range 2–3.5) and suggested the patient contact his warfarin provider regarding whether the dose should be increased until shortly before the next treatment. Anesthesiology felt comfortable with the INR level, and the patient received an ECT treatment (his thirteenth maintenance treatment). The patient's next maintenance treatment was in late September 2010. After the ECT treatment, the patient went into rapid atrial fibrillation with heart rate to 140. He was treated with intravenous esmolol and reverted back to a normal sinus rhythm.

## **Inspection Results**

### **Issue 1: Medical Optimization of ECT Patients**

We did not substantiate the allegation that a psychiatrist at the facility did not medically optimize patients prior to performing ECT treatments and more specifically, that the psychiatrist did not treat patients with their usual cardiac and anti-hypertensive medications on the morning of ECT treatment resulting in adverse events for two patients.

Patient 1 was a medically complex patient with a complicated MH presentation and a history of having had multiple ECT treatments with good response. Prior to re-initiation of ECT in June 2010, he was evaluated by internal medicine and anesthesiology and had relevant laboratory and radiographic studies as clinically indicated. The patient suffered a stroke approximately one and a half days following an ECT treatment in mid-June 2010. The BCMA history for the day of the ECT treatment showed that the patient received his 9:00 a.m. dosage of metoprolol at 6:26 a.m. the morning of the treatment, in advance of his ECT treatment that began at 10:56 a.m.

After experiencing the stroke, the patient ultimately stabilized medically over the next few months but continued to experience MH difficulties. His family desired to pursue ECT treatment given his past response. After re-evaluation, he resumed ECT treatments in mid-August.

Patient 2 had a history of paroxysmal atrial fibrillation and had undergone a left atrial ablation procedure in July 2010 at the system. Prior to switching from receiving maintenance ECT at White River Junction VAMC to receiving treatments at the system in early August 2010, he was evaluated both by a system internal medicine attending physician for a pre-ECT evaluation and the following Monday by his cardiac electrophysiologist. The patient had an uneventful ECT treatment in August. After his September ECT treatment, the patient went into rapid atrial fibrillation, which resolved after treatment with intravenous esmolol (a beta blocker). The anesthesiologist noted that the patient did not take his metoprolol that morning. However, the psychiatrist (on whom the allegation is focused) documented in a treatment note that the patient reported, and

the EMR confirmed, that his cardiac electrophysiologist had stopped the metoprolol in early-August. We found the psychiatrist's note accurately reflected previous documentation and recommendations by the cardiac electrophysiologist. The psychiatrist also noted that since the patient was not currently on metoprolol, anesthesia could, for future treatments, consider giving some esmolol prior to the ECT stimulus to decrease blood pressure and tachycardia in response to the stimulus.

The next day, a cardiac electrophysiology consult was requested for advice as to whether continuing ECT in this patient was safe from a cardiac perspective and, if so, for advice regarding peri-ECT cardiac medication management. A few days later, the patient reported his mood was much better and that he hoped he would not need to stop ECT. The psychiatrist suggested that they re-schedule his next treatment until after evaluation by his cardiologist.

The patient was evaluated by the cardiac electrophysiologist in mid-October 2010. The cardiac electrophysiologist documented: “. . . Reviewing the procedure note it seems he had mild tachycardia and it seemed like a generally mild episode of atrial fibrillation. Beta blocker for ECT would be fine but would hold off on daily beta-blocker as his rate has been slow in past with symptomatic bradycardia. IV esmolol would be a good choice during ECT.” The patient resumed maintenance ECT treatments later that week.

In August 2010, the system's Chief of Staff asked a former director of the ECT program to review five acute and maintenance ECT cases and a system cardiologist to separately evaluate the management of cardiovascular medications during the pre-ECT NPO (nothing by mouth) period.

The former director of the ECT Program found that the:

. . . provider conducts a risk-benefit analysis that is individualized to each patient, and proceeds accordingly. In the records I reviewed, the instruction to hold morning doses of medications until after the procedure was, in my opinion reasonable.

The cardiologist was asked to review 10 patient records looking for problems or opportunities for improvement. The cardiologist was also provided with the APA Task Force report on ECT. The cardiologist subsequently replied that he had reviewed the patients' EMR and did not identify any problems. He suggested that the system consider adopting more uniform NPO orders. From the records reviewed, it seemed to the cardiologist that sometimes orders for NPO after midnight included all medications, and sometimes NPO after midnight pertained to only certain medications. The cardiologist commented that because the APA Task Force report suggests not holding cardiac medications, it might make sense to make this the uniform policy (that is, the default policy).

In September 2010, after discussion by MH personnel, the Chief of Staff, and anesthesia personnel, the system revised the May 2009 patient care memorandum on administration of ECT. The revision added a section entitled *Medication Management During the Course of ECT*, which is based on the APA Task Force on ECT recommendations. The added section includes subsections on general considerations, medications typically continued through the ECT course, medications decreased or withdrawn prior to or during an ECT course, pharmacologic augmentation of ECT, and pre-ECT orders. Item b of the subsection on pre-ECT orders states that “prior to ECT mornings, ECT patients should have received proper instructions or orders regarding medications being withheld or not withheld and medications that should be taken after ECT.”

## **Issue 2: ECT Consent and Knowledge of Right To Refuse Treatment**

We did not substantiate the allegation that a psychiatrist at the Brockton campus had given ECT to a patient without the patient’s consent and knowledge that the patient could refuse ECT.

The patient was a man in his 70s with a diagnosis of depression with psychotic features who was admitted to the inpatient MH unit at the Brockton campus in early November 2009. The patient described his mood as low with thoughts of crashing his car into a telephone pole. For the week prior to admission, he stopped taking his medications because he felt they had little effect on his mood and were causing bothersome side effects. The patient had been treated in the late 1990s with ECT with reportedly good results. In August 2009 he had been offered but refused ECT, and medication adjustments were tried.

The resident’s admission history and physical examination state that “although he refused to try ECT back in August of this year, he now states it may be his only choice.” In an assessment note on the day of admission, which was co-signed and discussed with a staff psychiatrist, the psychiatry resident noted in the treatment plan “consider ECT as it has been beneficial in the past and patient is currently willing.” The resident and staff psychiatrist notes document that the plan was reviewed with the patient. The next day, the ward attending sought an ECT consult since the patient was having little response to his current medication regimen, was hospitalized for suicidal ideation, had a history of non-response to several antidepressants, and a prior sustained beneficial response to ECT. A note from a second psychiatry resident indicated that “currently pt [patient] would like ECT as he has become severely depressed and having side effects from lithium and Paxil.”

The following day, the ward attending psychiatrist noted that patient was “still on board with ECT.” After a meeting with the patient the next day, the social worker documented that, “the patient continues to agree to begin ECT.” The following week, the patient was evaluated by a psychiatrist regarding ECT treatment. The consultation documents a

discussion by the psychiatrist of potential risks, noting “the patient appeared to have a clear understanding of these risks and gave verbal consent.”

In mid-November, the psychiatrist met again with the patient. The patient signed a written consent which was witnessed by a staff nurse. The nurse entered a separate progress note confirming that the patient met with the psychiatrist and that the nurse witnessed him sign an informed consent for treatment the next day.

The next day, the patient underwent his first ECT treatment. The patient underwent a second ECT treatment 3 days later. He reported feeling slightly better on the following day and learned that his next ECT treatment would be in 7 days (due to holiday scheduling). Later in the week, the patient was also transferred from an acute to a chronic inpatient MH unit. When interviewed by his new attending psychiatrist on admission the patient reported poor sleep, feeling sad continuously, and feeling life is not worth living.

Prior to undergoing his third ECT treatment, the psychiatrist asked the patient if he wanted to go up on the stimulus intensity, but the patient elected not to “as he is finding his increased memory difficulties problematic, and didn’t wish to risk a further increase in these.”

In early December 2009, the attending psychiatrist on the new ward documented that the patient seemed better than when transferred, but the patient said he was still depressed, was not sleeping, and laid in bed during the day thinking depressive thoughts. “Nevertheless, he does say he feels the ECT is helping him and that he needs 12 more treatments.” He underwent ECT treatment number four the following morning. Three evenings later, a ward nurse noted that the patient was awake at 10:30 p.m. and when asked if everything was okay, he stated that he was a little worried about the ECT treatment scheduled for the next day. Due to circumstance unrelated to this patient, the anesthesiologist cancelled all ECT treatments scheduled for the following day, and the patient’s next treatment was re-scheduled. Three days later, the patient underwent his fifth ECT treatment. In the pre-treatment “time out” section of the treatment note, the psychiatrist documented that the patient verbally affirmed his continuing consent for ECT.

Four days later he was sent to the Jamaica Plain facility for his sixth treatment. The psychiatrist who had performed the previous five treatments was away that day, and a different psychiatrist would be performing the treatment. During the pre-ECT “time out,” the patient verbally declined his continuing consent for ECT. The nursing pre-ECT note also documented that the patient stated, “I don’t want to have it done.” The treatment was not performed and was cancelled. That evening, referring to the ECT treatment, the patient told a ward nurse, “I am going to refuse it again on Thursday.”

A medical student documented having accompanied the patient to the ECT appointment. The student wrote:

Prior to being brought to the setup room, he seemed mildly annoyed but yet [was still] planning on doing the procedure and was in a good mood. When he was brought back to the ECT area, the doctor went through time-out and asked him what his name and social security number were, where he was, and what he was there for, questions which he got all right. Then the doctor asked him if he wanted to continue on to the procedure, and [the patient] said “no.” One of the nurses asked if he was kidding or not, and he said “no.” He said “I feel fine enough without it.” Because he would not consent to the procedure, his ECT session was cancelled. The doctor asked him if he felt this way this morning before leaving the Brockton VA, and he said “yes,” and when asked why he didn't say something then he replied “I didn't know I had that option.” When asked if he would return for his Thursday appointment, he said “we'll see how I feel.”

The patient decided not to have further ECT treatments, and his future ECT appointments were cancelled. He desired to return home to the community residential care program at which he resided. The patient was discharged in late December. The chronic ward attending psychiatrist's brief summary of the patient's hospital course in the discharge note states the patient “came to us with depression on ECT treatment. However, once he found out that it was his choice, he declined treatment and didn't want it anymore.”

We interviewed the attending psychiatrist from the acute ward who asserted that, consistent with documentation in the EMR, he talked with the patient regarding ECT treatment prior to each treatment and at no point did the patient refuse. He reported that it is also his understanding that before each ECT treatment, the providers ask the patient if it is okay to go ahead with treatment. In this patient's case, the patient had improved and then declined ECT treatment at the time of the last treatment. The attending psychiatrist from the chronic ward reported that if a patient told her that he did not want ECT, she would not do it. In addition, she expressed her opinion that the psychiatrist who performed the first five treatments would not disregard a patient's wishes. In support of this assertion, she commented that recently she had consulted the psychiatrist about a patient with a health care proxy, and the psychiatrist had told her that she would not do ECT on a patient who did not want ECT, even if there was a proxy who advocated for ECT treatment.

We interviewed one of the psychiatry residents who had treated the patient. The resident stated that although she was not involved in the consenting process, she would be involved in preparing the transfer orders from Brockton to Jamaica Plain which generally prompts a discussion with the patient to make sure that he is ready and willing to go for ECT treatment. The psychiatry resident asserted that, in her experience working with the

Brockton unit, staff would not send a patient who did not want to go for ECT treatment to Jamaica Plain.

In summary, we do not know in hindsight what the patient thought or what his understanding was during the period of this hospitalization of his right to refuse ongoing treatments. The EMR indicated that the patient had decision making capacity. Both verbal and signed consents for ECT were obtained. Several EMR notes from different providers indicated that ECT was serially discussed with the patient, that he was aware that he was having ECT treatments, and that he was agreeable to ECT. Within the prior 6-month period, he had previously exercised his right to decline ECT. After the fifth treatment during the hospitalization described in this section, the patient asserted his desire to refuse treatment, and consequently further treatments were cancelled.

### **Issue 3: ECT Machine Maintenance and Equipment Failure**

We substantiated the allegation that the ECT machine had not been sent to the manufacturer for required maintenance and that local maintenance of the ECT machine by system staff does not substitute for manufacturer performed maintenance. We substantiated that some ECT treatments were re-scheduled because of difficulty with stimulus initiation. The complainant and ECT/anesthesia clinical personnel differed in their characterization of the frequency of these occurrences.

We called the manufacturer to ascertain the recommended maintenance schedule for the ECT machine. For the model that was in service at the Jamaica Plain campus at the time of the allegations, the manufacturer recommends that medical center biomedical technicians, or other appropriate personnel, complete an on-site functional performance check every 6 months and send the machine to the factory for a full quality control check every 2 years. The system acquired the ECT machine in November 2003. The recommended useful life for the machine is up to 13 years. Biomedical maintenance records indicate that between December 2003 and January 2010, local functional performance maintenance was conducted on an annual basis.

The complainant alleged the machine failed to deliver a stimulus on multiple occasions, which required cancellation and re-scheduling of treatments after patients had received anesthesia for the treatment. Reportedly, patients seemed “okay” and subsequently received the number of treatments prescribed. ECT clinical personnel and staff reported difficulty with stimulus initiation, which they characterized as periodic and sporadic, and which resulted in cancellation and re-scheduling of some treatments after patients had received anesthesia.

The repair history indicates work orders were completed in June and August 2009. In November of 2009, the machine was sent to the manufacturer for a quality control check. A failed capacitor on the power supply board was diagnosed and replaced. Final test results reportedly fell within acceptable ranges with the unit performing to specification,

and the unit was returned to the system in December 2009. A new ECT machine was acquired in May 2010 and subsequently placed in service with the old machine used as a back-up.

We were unable to reconcile the disparity between the frequency of ECT equipment malfunction reported to us by the complainant and by ECT/anesthesia staff members. We substantiated through our interviews and our electronic medical record reviews that some patient treatments were cancelled as a result of difficulty with stimulus initiation. We found that the ECT machine underwent local maintenance annually. We substantiated the allegation that the machine had not been sent to the manufacturer “in years” for a recommended quality control check.

#### **Issue 4: Alleged ECT Research Study Improprieties**

We did not substantiate the allegation that a psychiatrist was engaged in research on a MH Diagnostic Study sponsored by a pharmaceutical company and, that because the company purportedly wanted its proprietary medication to be used in lieu of ECT, the psychiatrist included a patient in the study who was not medically optimized so that the risk of cardiac side effects with ECT would be emphasized.

The psychiatrist who is the subject of this allegation reported that she had not been involved in clinical research in many years. She stated that she has no research projects or research funding and adamantly denied having any involvement with a pharmaceutical company.

We obtained and reviewed a list of all active 568 IRB protocols for the system and IRB protocols in place during the time period relevant to the allegation. The psychiatrist, who is the subject of this allegation, is not listed as a principal investigator in any of the IRB protocols. We interviewed the IRB administrator who had been with the system for several years. From his recollection he did not recall this psychiatrist as having been involved in any IRB research protocols during his tenure. Upon review of the IRB protocol list, we did not find any research protocols involving ECT, the medication, or titled a “Mental Health Diagnostic Study.”

On review of eight EMRs of patients who received ECT during the relevant time frame, we did find a progress note on two patients that was titled “Mental Health Diagnostic Study.” Each of the two notes listed the results of several specific MH standardized assessment questionnaires. For example, the Beck Depression Inventory<sup>®</sup> II (BDI<sup>®</sup>-II) is a 21 multiple choice question instrument that is used to help clinicians assess depressive symptoms. The inventory may be self-administered or administered by a clinician. Under the listing of the item responses, the progress note indicates that the BDI<sup>®</sup>-II was “reproduced by permission. Copyright [Copyright] 1991. By the Psychological Corporation. All rights reserved.” Similarly, the PHQ-9 is a nine-item depression scale of the Patient Health Questionnaire. The PHQ-9 is based on diagnostic criteria for major

depression in the Diagnostic and Statistical Manual Fourth Edition (DSM-IV).<sup>20</sup> The PHQ-9 is adapted from another instrument, the PRIME-MD<sup>®</sup>, and was developed by Dr. Robert L. Spitzer, Dr. Janet B.W. Williams, and Dr. Kurt Kroenke with an educational grant from Pfizer Inc. Under the listing of item responses in a patient's VA progress note entitled Mental Health Diagnostic Study, the note states "copywrite 2001 Pfizer Inc. Prime-MD is a trademark of Pfizer Inc."<sup>21</sup>

We spoke with the psychiatrist who was the focus of this complaint who reported that the software, *Mental Health Assistant*, is available at VAMCs for clinicians to use to enter results of MH assessment instruments. The software places results into the progress note section of the patients' EMRs. The psychiatrist did not know how the note gets titled "Mental Health Diagnostic Study" and denied involvement in any kind of research study. We spoke with a psychologist at the facility who reported that instruments from the *Mental Health Assistant* software are incorporated into progress notes but could not recall what or how the notes are titled. The psychologist interpreted the word "study" within the context of "MH Diagnostic Study" to mean "test" in the way that a physician might list the results of bloodwork as a "test" or "study." To this psychologist's awareness, the psychiatrist had not been performing or involved in a diagnostic research study.

We spoke with the VANMHDI who verified that the *Mental Health Assistant* software package is available at VAMCs. Clinicians can perform pen and paper versions of standardized assessment questionnaires and then enter the results into the software package, or the patient can be asked to complete the questionnaire directly into the *Mental Health Assistant* once access is established with the clinician. The software stores the results to enable clinician monitoring of symptom assessment over time and places a progress note for the set of assessments performed that day into the progress note section of the patient's EMR. The VANMHDI verified that currently the title for all such progress notes is standardized across the system. All such assessments use the title "Mental Health Diagnostic Study," which was assigned by the National VA Standards and Terminology Group.

We did not substantiate the allegation regarding improper inclusion in an ECT or pharmaceutical company sponsored research study.

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<sup>20</sup> Spitzer R, Kroenke K, Williams J. Validation and utility of a self-report version of PRIME-MD: the PHQ Primary Care Study. *Journal of the American Medical Association* 1999; 282: 1737–1744.

<sup>21</sup> Kroenke K, Spitzer R L, Williams J B. The PHQ-9: Validity of a Brief Depression Severity Measure. *Journal of General Internal Medicine* 2001; 16(9): 606–613.



## **Issue 5: Alleged Nepotism and Disparity in Chronic MH Unit Census**

We did not substantiate the allegation that one of the chronic inpatient units received fewer transfers/admissions and maintained a lower patient census in exchange for provision by a unit clinician of research training to a relative of the Director of Inpatient MH. We did not substantiate the allegation that the relative's e-mail and EMR access breached the system's patient confidentiality policies.

We interviewed MH clinicians and inpatient MH leadership at the Brockton campus regarding the process for assigning admissions and intra-ward transfers to attending psychiatrists.

The researcher for whom the relative worked came to the system from an academic medical center in January 2009. In addition to continuing research work related to ongoing research grants, the researcher was also assigned clinical duties as an attending physician for a chronic MH unit at the Brockton campus. In her previous position at the academic medical center, the researcher had both research assistants and administrative support. The researcher reported that the transition to the VA was initially challenging and that after coming to the VA, she did not have administrative support or a research assistant. The researcher needed assistance and applied for a National Institutes of Health (NIH) support grant for summer students. The researcher learned of two possible students through word-of-mouth. One of these students was the relative of the Director of Inpatient MH. The researcher emphasized that she had initiated looking for students to help as research assistants and that the Director of Inpatient MH had not initiated or suggested that the researcher hire her relative.

Ultimately, the researcher did not get the NIH grant. However, because she needed assistance and felt that she had, in effect, recruited the two students, she spoke with the system's Chief of Research who agreed to allocate some start-up funding to aid in the researcher's transition to the system.

We reviewed human resources paperwork related to the relative of the Director of Inpatient MH. The relative, a college student, had worked as a volunteer at a community hospital from 2004 through 2008. In the spring of 2009, the relative applied for a volunteer research assistant position at the Brockton campus. In the human resources paperwork, the relative accurately acknowledged having a relative who worked for the agency and organization to which she was applying, and she appropriately indicated her relationship to the employee. The relative was initially assigned to the facility as a research assistant for 2 months in 2009. As a without compensation status employee, she received no monetary compensation and was not entitled to leave, retirement, or other Federal benefits other than subsistence (meals).

The relative reportedly helped with organizing files and conducting background research for a paper the researcher was working on. The relative was not involved in clinical

patient care and was peripheral to the clinical functioning of the unit. We confirmed that the relative had EMR access and a system e-mail account. The researcher reported that the volunteer research assistant used the EMR access to assist her in identifying eligible and appropriate research participants. VA requires that all employees, including volunteers, without compensation employees, and students complete mandatory periodic security and privacy awareness training and sign *VA National Rules of Behavior* annually.<sup>22</sup> The relative completed all required training and signed required forms, including a *Statement of Commitment and Understanding for VA Trainees*. The relative was later hired as a paid research assistant for a portion of the summer of 2009 with start-up funds.

The researcher denied any quid pro quo relationship or impact on unit census. The researcher reported that her specialization was young-middle aged patients with serious mental illness, such as schizophrenia. The unit to which she was assigned is more predominantly older adults. Although the researcher reported that she was proactive about accepting patients from the acute units, as she was hoping to have a more heterogeneous caseload. It was also her perception that she tended to get more admissions and transfers than other clinicians.

We could not find evidence to link the relative's presence to quid pro quo favoritism by MH leadership in determining the distribution of admissions/transfers to each chronic unit.

## **Issue 6: EMR Access Issues**

We substantiated the allegation that a psychiatrist at the Brockton campus had initiated EMR notes under other clinicians' accounts without their knowledge or consent. However, we did not substantiate that a clinician could sign a note for another provider, which would then enter the note into the EMR, or that this psychiatrist had ADPAC privileges allowing in-depth computer access.

The OIG was forwarded an e-mail string dated and starting on January 15, 2011. A psychiatrist sent an e-mail to a psychiatry resident and courtesy copied the e-mail to several psychiatry attending physicians at the Brockton campus stating that 2 nights earlier the psychiatric officer of the day (POD) was not notified that a patient had been sent by ambulance to an outside hospital by the MOD. As a result, there was no EMR documentation by the POD regarding transfer to the outside hospital.

According to documentation we obtained, the POD, a resident, reported that a progress note had been initiated under her name without her knowledge. In her e-mail, the resident stated, "I did not write this note, but CPRS [i.e., the EMR] is notifying me to sign it. I have no idea who this patient is, had no idea he was being discharged, and don't

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<sup>22</sup> VA Handbook 6500 Appendix G, *Department of Veterans Affairs (VA) National Rules of Behavior*, September 18, 2007.

know if I should sign this discharge note that some unknown person wrote under my name.” The psychiatrist told the POD that she (the psychiatrist) had generated the note so that the EMR could be complete.

The psychiatrist (on whom the allegation is focused) acknowledged opening notes for other providers in the EMR but emphasized that she cannot sign notes for other providers. She denied having access to any other clinicians’ access codes. The psychiatrist demonstrated to us that anyone with EMR access can start a note for another provider, and it does not require special access to do so. She reported that she uses this option to remind residents that they need to document a note in the EMR. When she starts a note, she saves it, and an electronic alert is sent to the resident. The resident can then go into the note, write what they need to write, or edit what is there, and then sign the note. Even though the psychiatrist opens the note, she reported that the resident owns control of the note.

We interviewed the POD who reported that she became aware of the note when she received an alert from the EMR system. The POD reported that the psychiatrist who sent the e-mail told her that she could either sign the note or write and sign her own note. The POD had not shared her EMR access information with the psychiatrist. The POD reported that the psychiatrist apparently opens notes for resident physicians to cue them that they need to complete notes; however, the resident ultimately needed to sign the note. The resident reported that other attending psychiatrists at the facility do not open or initiate notes for residents.

The Director of Inpatient MH at the Brockton campus told us that she was not aware that one provider could open a note in CPRS for another provider and did not believe it was advisable.

We interviewed the system’s CISM to explore access control issues. The CISM confirmed that one feature of the EMR is that a provider can open a note and change the author of the note to someone else. The CISM verified that providers did not need any special access to do this. Further, the CISM did not feel that this was an EMR vulnerability because the EMR would not allow the provider to sign a note for another provider. By accessing the underlying EMR software, the Veterans Health Information Systems and Technology Architecture, both the name of the logged in provider who opened the note and the listed author can be seen. However, the clinician-user’s EMR screen will only show the listed authors name. The note would be visible to the provider who opened the note and the person they listed as the author but would not be generally visible/readable to other EMR users until the listed author signed the note. Each clinician author has his or her own unique access code which allows the individual to sign a note. In addition, they may co-sign notes for which they have been designated by the note’s author to be a co-signatory. For example, a resident physician might write a note and designate their attending physician as the co-signer.

We asked for clarification regarding the role of the ADPAC. The CISM explained that the ADPAC is responsible for maintaining the many clinical applications within the EMR and training staff on specific applications. ADPACs do not have access codes for other people except temporary codes when establishing new accounts. The CISM reported that the psychiatrist had never been an ADPAC. The CISM reported that “superusers” have learned all the EMR applications and promote their use within a service but do not have special access or privileges that allow in-depth access.

In summary, the psychiatrist did have a practice of occasionally initiating EMR notes for other clinicians (mainly resident physicians) as a prompting mechanism. However, the psychiatrist did not have access to other clinicians’ accounts and could not sign the notes that she opened under the names of other clinicians and thereby enter them into the official EMR.

## Conclusions

We did not substantiate that a psychiatrist did not medically optimize two patients prior to ECT resulting in adverse events. Staff appropriately treated both patients on the morning of ECT. The first patient did receive his anti-hypertensive medication on the day of treatment. The second patient had a history of atrial fibrillation independent of ECT, and his beta-blocker had been previously discontinued by his cardiologist prior to the ECT treatment in question.

We did not substantiate that staff provided ECT treatment to a patient without obtaining his consent or informing the patient that he could refuse treatment. Staff documented that the patient had capacity to make decisions. The EMR also reflects several provider-patient discussions regarding ECT, as well as the patient’s decisions to sometimes accept and, at other times, refuse ECT treatment. This is not withstanding that a medical student did, in one note, document the patient as stating “I didn’t know I had this option.”

We substantiated that the ECT machine was not sent to the manufacturer for maintenance, as recommended, and that some ECT treatments were re-scheduled because of equipment malfunctions. The system’s biomedical staff performed annual and routine maintenance on the machine; however, this did not substitute for manufacturer maintenance.

We did not substantiate that a psychiatrist did not optimize a high risk patient prior to ECT in effort to emphasize ECT side effects and promote a company’s drug in lieu of ECT. We also did not substantiate that the psychiatrist was surreptitiously conducting a MH Diagnostic research study.

We did not substantiate that an inpatient MH unit had a lower census to benefit a researcher and a relative of the Inpatient MH Director. In fact, it was the researcher’s perception that she attempted to accept more patients to the MH unit in an effort to have a

more heterogeneous caseload. We also did not substantiate that the relative's e-mail and EMR access breached the system's confidentiality policies. The MH Director's relative appropriately acknowledged her relationship with the MH Director upon application, worked initially as a volunteer and later an unpaid research assistant, and completed all VHA requirements to access e-mail and other electronic records.

We substantiated that a psychiatrist initiated, but did not complete, EMR notes for residents she supervised. The notes could not be completed until signed by the residents. We did not substantiate the allegation that the psychiatrist had special privileges which allowed in-depth computer access.

## **Recommendations**

We recommended that the System Director implement procedures to ensure that the manufacturer's recommended maintenance for the ECT machine is followed.

## **Comments**

The VISN and System Directors agreed with the findings and recommendations and provided acceptable action plans. (See Appendixes A and B, pages 26–28 for the full text of their comments.) The System Director has implemented processes to ensure that the recommended maintenance for the ECT machine is included in the annual preventive maintenance procedure. We will follow up until the planned actions are completed.



JOHN D. DAIGH, JR., M.D.  
Assistant Inspector General for  
Healthcare Inspections

## VISN Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** August 19, 2011

**From:** Director, VA New England Healthcare System (10N1)

**Subject:** **Healthcare Inspection—Alleged Quality of Care Issues in the  
Electroconvulsive Therapy Program, VA Boston Healthcare System,  
Boston, MA**

**To:** Director, Baltimore Office of Healthcare Inspections (54BA)

**Thru:** Director, Management Review Service (10A4A4)

I concur with the findings of the report of the Healthcare Inspection - Alleged Quality of Care Issues in the Electroconvulsive Therapy Program submitted to the Office of the Inspector General.

*(original signed by :)*

Michael Mayo-Smith, MD

Director, VA New England Healthcare System (10N1)

## System Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** August 19, 2011

**From:** Director, VA Boston Healthcare System (523A4/00)

**Subject:** **Healthcare Inspection—Alleged Quality of Care Issues in the  
Electroconvulsive Therapy Program, VA Boston Healthcare System,  
Boston, MA**

**To:** Director, VA New England Healthcare System (10N1)

I concur with the findings of the report of the Healthcare Inspection - Alleged Quality of Care Issues in the Electroconvulsive Therapy Program submitted to the Office of the Inspector General.

*(original signed by:)*

Michael M. Lawson

Director, VA Boston Healthcare System (523A4/00)

## **Director's Comments to Office of Inspector General's Report**

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

### **OIG Recommendations**

**Recommendation.** We recommended that the System Director implement procedures to ensure that the manufacturer's recommended maintenance for the ECT machine is followed as prescribed.

**Concur**

**Target Completion Date:** 9/30/2011

### **System's Response:**

#### **Comments:**

- a. Upon review, the system's annual preventive maintenance procedure included all of the manufacturer recommendations except for "Central and Safety Processor software will be upgraded to the current versions." These procedures were followed with the ECT equipment with the newer ECT equipment receiving preventative maintenance in June 2011 and the older ECT receiving preventative maintenance in January 2011.
- b. A CE supervisor contacted the manufacturer and determined that a new version of central and safety processor software was released 2 months ago, with the last software upgrade before that, in 2002. Both VA BHS ECT devices have the 2002 software and are being scheduled to be upgraded to the latest software.

#### **Action Plan:**

- a. Both the primary and back-up ECT devices are upgraded to the latest software versions by September 30, 2011.
- b. The following item will be added to a written VA BHS Clinical Engineering annual preventive maintenance procedure by August 26, 2011, "Verification with the manufacturer that the device is at the current version of central and safety processor software and upgraded as available."

**Status:** In process.



## **OIG Contact and Staff Acknowledgments**

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OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Nelson Miranda, Project Leader Frank Miller, PhD, Team Leader Alan Mallinger, MD Claire McDonald, MPA Michael Shepherd, MD

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